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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,280	04/26/2006	Takeshi Tabira	40072-0026US	3468

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EXAMINER	
SHEN, WU CHENG WINSTON	

ART UNIT	PAPER NUMBER
1632	

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10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,280	TABIRA ET AL.	
	Examiner	Art Unit	
	WU-CHENG Winston SHEN	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the restriction requirement mailed on 09/01/2009, Applicant cancels previously restricted claims 1-18 and added new claims 19-29. For the clarity of record, the restriction requirement is revised in this office action.

This application 10/560,280 is a 371 of PCT/JP04/08224 filed on 06/11/2004

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 19-21 and 29, drawn to a method for treating Alzheimer's disease, comprising administering to a subject an adeno-associated virus vector which expresses β-amyloid peptide in intestinal cells in a therapeutically effective amount, wherein the adeno-associated virus vector comprises DNA encoding said β-amyloid peptide and DNA encoding a signal peptide capable of extracellularly secreting said β-amyloid peptide, in an operative form, wherein said β-amyloid peptide comprises the amino acids 4 to 10 of the amino acid sequence as shown in SEQ ID NO: 2, and wherein the DNA encoding said β-amyloid peptide comprises the nucleotides 10 to 30 of the nucleotide sequence as shown in SEQ ID NO: 1.

II. Claims 19, 22, 23, and 29, drawn to a method for treating Alzheimer's disease, comprising administering to a subject an adeno-associated virus vector which

expresses β-amyloid peptide in intestinal cells in a therapeutically effective amount, wherein the adeno-associated virus vector comprises DNA encoding said β-amyloid peptide and DNA encoding a signal peptide capable of extracellularly secreting said β-amyloid peptide, in an operative form, wherein said β-amyloid peptide comprises the amino acid sequence as shown in SEQ ID NO: 2, and wherein the DNA encoding said β-amyloid peptide comprises the nucleotide sequence as shown in SEQ ID NO: 1.

III. Claims 19, 24, 25, and 29, drawn to a method for treating Alzheimer's disease, comprising administering to a subject an adeno-associated virus vector which expresses β-amyloid peptide in intestinal cells in a therapeutically effective amount, wherein the adeno-associated virus vector comprises DNA encoding said β-amyloid peptide and DNA encoding a signal peptide capable of extracellularly secreting said b-amyloid peptide, in an operative form, wherein said β-amyloid peptide comprises the amino acid sequence as shown in SEQ ID NO: 4, and wherein the DNA encoding said β-amyloid peptide comprises the nucleotide sequence as shown in SEQ ID NO: 3.

IV. Claims 19 and 26-29, drawn to a method for treating Alzheimer's disease, comprising administering to a subject an adeno-associated virus vector which expresses β-amyloid peptide in intestinal cells in a therapeutically effective amount, wherein the adeno-associated virus vector comprises DNA encoding said β-amyloid peptide and DNA encoding a signal peptide capable of extracellularly secreting said b-amyloid peptide, in an operative form, wherein said signal peptide comprises the amino acid sequence as shown in SEQ ID NO: 6, and wherein the DNA encoding said signal peptide comprises the nucleotide sequence as shown in SEQ ID NO: 5.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(i) With regard to restriction between Groups I-IV, Applicant's attention is directed the M.P.E.P cited below.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, the Commissioner has stated that, "The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371." See Examination of Patent Applications Containing Nucleotide Sequences 1316 OG 122 (March 27, 2007). **For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.**

In instant application, it is noted that SEQ ID No:1 encodes SEQ ID No:2; SEQ ID No:3 encodes SEQ ID No:4; SEQ ID No:5 encodes SEQ ID No:6. SEQ ID No: 3 is part of SEQ ID No: 1 and SEQ ID No: 4 is part of SEQ ID No: 2. Groups I-IV are patentably distinct in term of what nucleotide sequences are comprised in the claimed adeno-associated virus vectors used for claimed methods for treating Alzheimer's disease.

(ii) Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups, as stated in claim 19, is a method for treating Alzheimer's disease, comprising administering to a subject an adeno-associated virus vector which expresses β-amyloid peptide in intestinal cells in a therapeutically effective amount, wherein the adeno-associated virus vector comprises DNA encoding said β-amyloid peptide and DNA encoding a signal peptide capable of extracellularly secreting said β-amyloid peptide, in an operative form. However, this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art. In this regard, **Kuwako et al.** teaches the active steps of claim 19 of instant application. Kuwako et al. teaches that Alzheimer's disease (AD) is a neurodegenerative disease and studies of the molecular mechanism of AD indicates that overexpression of wild-type amyloid precursor protein (APP) in postmitotic neurons induces cleavage-dependent activation of caspase-3 both in *vivo* and *in vitro* by recombinant adenovirus, which is an obvious variant of adeno-associated virus, expressing wild-type APP and its Aβ (1-20) lacking mutant (APPΔAβ20), and an APP-accumulating neurons *in vitro*, caspase-3 is activated in a cleavage dependent manner, and a caspase-3 inhibitor significantly reduces the

severity of degeneration exhibited by APP overexpressing neurons (See abstract and material and Methods, Kuwako et al., Activation of calpain in cultured neurons overexpressing Alzheimer amyloid precursor protein, *Brain Res Mol Brain Res.* 107(2):166-75, 2002)

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, Jr. can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wu-Cheng Winston Shen/
Patent Examiner
Art Unit 1632